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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,933	03/27/2007	Galit Levin	85189-13500	2953

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PATENT DEPARTMENT
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EXAMINER	
SCOTT, BRANDY C	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
09/27/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/561,933	LEVIN ET AL.	
	Examiner	Art Unit	
	BRANDY C. SCOTT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 August 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Nowhere in the original claims, specification, or drawings does Applicant disclose topically applying a dermatologically effective amount of a composition "without the application of electrical energy."

3. Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is not clear how Applicant can claim that the dermatological composition can be topically applied "without the application of electrical energy" when the application of the composition is taught to occur immediately after an ablation technique which would inherently apply electrical energy to the skin.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 14-17, 19, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-based vaccines" to Bramson (Bramson) in view of U.S. Patent No. 2002/0161324 to Henley (Henley'324) in view of U.S. Patent No. 6,302,874 to Zhang (Zhang).

In Reference to Claims 14-17, 19, and 22-24

Bramson teaches a system and method for intradermal delivery of an agent comprising: pre-treating skin by generating a plurality of micro-channels in the skin (Figure 1) by an apparatus comprising: an electrode cartridge (microporation tip comprising ceramic substrate, p. 259, col. 1) comprising a plurality of electrodes (80 micron tungsten wires strapped on the substrate are the electrodes, p. 259, col. 1) to be oriented generally perpendicular to the skin (even though the tungsten wires are strapped around a ceramic substrate, they still have a perpendicular component to them due to the 80 micron diameter they possess. When the substrate with the tungsten wires is placed in the vicinity of the skin, the 80 micron diameter of the wire protrudes perpendicularly from the substrate towards the skin); and a main unit comprising a

control unit (p. 258-259; laptop computer, microprocessor control circuitry, three-axis stepper motor assembly with microporation tip holder) which is adapted to apply electrical energy between the two or more electrodes in the vicinity of the skin, enabling ablation of the stratum corneum (p. 259, col. 1, lines 3-9), thereby generating a plurality of microchannels having a diameter of about 10-100 microns and a depth of 20-300 microns (p. 259, col. 1, lines 3-23, see MPEP §2144.05 for overlap of ranges). Bramson further teaches applying a vaccine via the use of a patch applied to the skin after the channels are created (p. 259, col. 1) and further teaches wherein the electrode cartridge (tip comprising the substrate with tungsten wires) is attached to the control circuitry via copper traces on each side of the substrate. Bramson fails to teach a cosmetic composition comprising a cosmetic agent and a carrier devoid of permeation enhancers is applied to the skin after the channels are created and fails to explicitly teach wherein the electrode cartridge is removably attached to the main unit so that it may be discarded after use.

Henley'324 teaches an electrokinetic delivery device (Figure 2) that comprises a main unit (portion 20) that houses the power source and the control circuitry and a separate distal portion (portion 22) that houses the active electrode and a counter electrode (paragraphs [0035-0036, 0039]) and is therefore an electrode cartridge. This electrode cartridge is detachable from the main unit (portion 20) and is connected via electrical contacts 42 in the electrode cartridge mating with electrical sockets 44 in the main unit portion 22 (Figure 2). Henley teaches the electrode cartridge being detachable from the main unit in order to enable the main unit that contains all the

electronics and power source to be reusable multiple times while the electrode cartridge can be disposed of or replaced separately after each individual use (paragraph [0009]).

Zhang teaches producing transient pores in the skin to facilitate the transdermal delivery of a cosmetic agent composition (col. 7, lines 6-13) comprising at least one cosmetic agent (col. 7, lines 45-48), an acceptable carrier (col. 6, lines 42-53) that is devoid of permeation enhancers (col. 8, lines 33-54, whereby the permeation enhancer is described as being optional), one of the claimed components in claim 9 (col. 1, line 40), and is in one of the claimed forms of claims 12 and 13 (col. 6, lines 53-57) and further teaches wherein the composition is contained within a patch reservoir that can be attached to the skin (col. 14, lines 20-23). Zhang teaches this patch reservoir composition in order to provide a means to improve the appearance of the skin (col. 1, lines 13-17) as well as treat a variety of skin conditions (col. 5, lines 46-47).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Bramson to have the copper traces that provide the connection between the electrode cartridge (ceramic substrate with tungsten wires) and the main unit (control circuitry) be detachable connections like electrical contacts mating with electrical sockets as taught by Henley'324 in order to enable the main unit that contains all the electronics and power source to be reusable multiple times while the electrode cartridge can be disposed of or replaced separately after each individual use (paragraph [0009]).

Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device and method of Bramson to

apply the patch containing the cosmetic agent and carrier as taught by Zhang to the skin after micro-channel formation in order to provide a means to improve the appearance of the skin (col. 1, lines 13-17) as well as treat a variety of skin conditions (col. 5, lines 46-47).

5. Claims 18, 20, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enabling topical immunization via microporation: a novel method for pain-free and needle-free delivery of adenovirus-based vaccines" to Bramson (Bramson) in view of U.S. Patent No. 2002/0161324 to Henley (Henley'324) in view of U.S. Patent No. 6,302,874 to Zhang (Zhang) as applied to claim 1, 5, 14, and 15 above, and further in view of U.S. Patent No. 6,477,410 to Henley (Henley'410).

In Reference to Claim 18

Bramson in view of Henley'324 and Zhang teaches the device and method of claims 5 and 15 (see above) but fails to teach wherein the cosmetic agent is hydroquinone. Henley'410 teaches delivery of cosmetic agents to the skin that can include hydroquinone in order to remove pigmentation from hyperpigmented areas of the skin (col. 4, lines 65-66). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device and method of Bramson in view of Henley'324 and Zhang to deliver hydroquinone as taught by Henley'410 in order to remove pigmentation from hyperpigmented areas of the skin (col. 4, lines 65-66). Further, it has been held to be within the general skill of a worker in the

art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416).

In Reference to Claims 20 and 21

Bramson in view of Henley'324 and Zhang teaches the device and method of claims 1 and 14 (see above) but fails to teach wherein the composition further comprises an antibacterial agent. Henley'410 teaches delivery of antibacterial agents to the skin in order to inhibit bacterial growth (col. 2, lines 9-11; col. 4, lines 49-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device and method of Bramson in view of Henley'324 and Zhang to include an antibacterial agent in the composition as taught by Henley'410 in order to inhibit bacterial growth (col. 2, lines 9-11; col. 4, lines 49-50). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice (*In re Leshin*, 125 USPQ 416).

Response to Amendment

6. In the response filed 7/12/2010, Applicant cancelled claims 1-13 and amended claim 14. Currently, claims 14-24 are under examination.

Response to Arguments

7. Applicant's arguments filed 7/12/2010 have been fully considered but they are not persuasive. First, Applicant argues that the finality of the present Office Action would be improper since the previous Examiner did not examine the current claims. However,

the current Examiner is maintaining the position of the previous Examiner that the claims had not been further amended in a way that would have changed the rejection at that time. Furthermore, the current claims submitted 7/12/2010 have been further amended beyond those amendments made 3/10/2010. Therefore, it is proper to make this action final and the finality of this Office Action is necessitated by the amendments filed 7/12/2010 further limiting the claims.

As to the arguments concerning the Non-Final Rejection of 3/12/2010, Applicant traverses the combination of Bramson, Henley '324, Zhang, and Henley '410. Applicant argues that the combination does not read on the invention as claimed since Bramson teaches a method for immunization and not a method for cosmetically augmenting the condition of the skin. However, Bramson does disclose pre-treating the skin by creating micropores and applying heat (electrical energy) to the skin. Applicant's own disclosure teaches that the delivery of electrical energy to the skin may have beneficial effects on the appearance of skin even without administering a cosmetic agent as the electrical energy may facilitate removing of dead keratinized cells (2007/0270732: ¶0025), thereby treating the skin. Since Bramson teaches creating pores and then delivering a composition through the pores, it would be obvious to one of ordinary skill in the art to use the created pores to deliver any composition, including the cosmetic agents disclosed in the secondary references. Furthermore, the ablation technique taught by Applicant produces electric heat energy that would inherently affect the uptake of the topical composition by the skin.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDY C. SCOTT whose telephone number is (571)270-7410. The examiner can normally be reached on Monday-Friday, 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. C. S./
Examiner, Art Unit 3767

/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767